

Applicant(s): P. Bonutti and M. Brillhart
Application No.: 10/630,321
Examiner: G. Jackson

Remarks

Claims 11-14, 17-20, and 27-34 are presented for the Examiner's review and consideration. Claims 11 and 27 have been amended, and claims 15, 16, 21-26, 35, and 36 are withdrawn. Applicants believe the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §102 Rejections

Claims 11, 14, 17, 18, 27, and 28 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,449,372 to Schmaltz *et al.* (hereinafter "Schmaltz"). In response, Applicant respectfully submits that this rejection should be withdrawn.

Schmaltz was filed on June 14, 1991 and is a continuation-in-part application of U.S. Patent Application No. 07/594,121 which was filed on October 9, 1990. The present application was filed on July 30, 2003 and is related to U.S. Patent Application No. 07/545,919 which was filed on June 28, 1990.

Based on the priority dates, Applicants respectfully submit that Schmaltz is not prior art to the present application. Accordingly, Applicants request withdrawal of this rejection.

Claims 11, 14, 17-20, 27-29, and 31-34 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,102,417 to Palmaz (hereinafter "Palmaz"). In response, Applicants respectfully submits that this rejection should also be withdrawn.

Palmaz discloses an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway. (col. 6, lns. 21-23). The prostheses have a biologically inert or biologically compatible coating placed upon wall surfaces of tubular shaped members. (col. 11, lns. 6-8). Examples of biologically compatible coatings would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polylacoides, and copolymers thereof. (col. 11, lns. 26-31).

Applicants, on the other hand, disclose, *inter alia*, an assembly for use in surgical applications in humans. The assembly includes a heat bondable material. (¶0007). The heat bondable material is preferably a polymeric or composite material suitable for surgical

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applications and implantations in humans, and may be a biodegradable material where such is called for by the application. (§0011). The heat bondable material can be softened and made flowable by the application of heat. (§0034). An almost limitless number of surgical devices can be constructed in accordance with the present invention. Items such as rods, bars, plates, or any type of construct usable in medical/surgical applications can be custom shaped or built up in accordance with the present invention. They can be made of polymers or composites which can readily be cut with a laser and also softened to custom fit. They can also include tissue ingrowth promoters, antibiotics, or other additives as desired. (§0047). The heat bondable material is non-flowable and non-adherent at room temperature. (§0048).

As such, Palmaz teaches an implant including an absorbable polymer coating placed upon wall surfaces of tubular shaped members. In contrast, Applicants' implant includes a heat bondable material which is bonded to an implant by the application of heat.

To highlight this distinction, Applicants have amended independent claims 11 and 27 to include, *inter alia*, a polymer material which is non-flowable and non-adherent at room temperature and becomes flowable, tacky, and adherent upon the application of heat. Applicants submit that claims 11 and 27 are patentable over Palmaz. Based on at least their dependencies, Applicants submit that claims 14, 17-20, 28, 29, and 31-34 are patentable as well.

35 U.S.C. §103 Rejection

Claims 12, 13, and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schmaltz or Palmaz in view of U.S. Patent No. 4,994,071 to MacGregor (hereinafter "MacGregor"). In response, Applicants respectfully submit that this rejection should be withdrawn.

MacGregor discloses a bifurcating stent for insertion into a branching vessel of a subject. (col. 2, lns. 24-25). The stent may be produced from a variety of materials, either alone or in combination, such as metals or alloys that can vary in their springiness, malleability, and response to temperature; polymers that can vary in their ability to bioabsorb or biodegrade; carbon; and ceramics. Various surface treatments can be applied to render the stents more biocompatible and to provide for the elution of drugs. (col. 5, lns. 38-49).

To establish prima facie obviousness of a claimed invention, all the claim limitations

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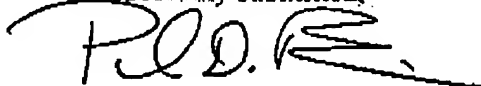
must be taught or suggested by the prior art. (MPEP §2143.03). As claims 12 and 13 depend from claim 11 and claim 30 depends from claim 27, Applicants contend that the rejected claims necessarily include all the elements of amended claims 11 and 27. Therefore, Applicants submit that claims 12, 13, and 30 are patentable over Palmaz in view of MacGregor. Applicants further contend that MacGregor fails to overcome the deficiencies of Palmaz with respect to amended independent claims 11 and 27.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$180 is believed to be due for an Information Disclosure Statement. A Credit Card Payment Form, PTO-2038, is provided herewith. Please charge any additional fees (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket no. 780-A02-015-10).

Respectfully submitted,



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